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- ☐ 1. [20040033240](#). 09 Jun 03. 19 Feb 04. Immunological combinations for prophylaxis and therapy of helicobacter pylori infection. Guy, Bruno, et al. 424/234.1; A61K039/02.
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File: USPT

Sep 23, 2003

DOCUMENT-IDENTIFIER: US 6623764 B1

TITLE: Biodegradable targetable microparticle delivery system

Drawing Description Text (32):

FIG. 20 shows the serum IgG antibody subtype responses in mice immunized subcutaneously (S.C.) or orally (I.G.) following various immunization protocols by the recombinant protein rUrease from Helicobacter pylori. Groups of 8 mice were immunized on days 1, 28 and 56 with 250 .mu.L of PBS pH 7.4, containing 10.0 .mu.g (S.C.) or 40.0 .mu.g (I.G.) of rUrease incorporated into PLGpS microparticles or 10.0 .mu.g (S.C.) or 40.0 .mu.g (I.G.) of rUrease formulated in the presence of DC-Chol, CT-X, PCPP or LT incorporated into PLGpS microparticles. Sera was obtained on day +85 and were evaluated for the presence of anti-rUrease IgG antibodies using an enzyme-linked immunosorbent assay (ELISA).



US006623764B1

(12) **United States Patent**  
Sokoll et al.

(10) **Patent No.:** US 6,623,764 B1  
(45) **Date of Patent:** \*Sep. 23, 2003

(54) **BIODEGRADABLE TARGETABLE  
MICROPARTICLE DELIVERY SYSTEM**

4,855,283 A 8/1989 Lockhoff  
5,399,665 A 3/1995 Barrera et al.  
5,593,778 A 1/1997 Kondo et al.  
5,625,030 A 4/1997 Williams et al.

(75) Inventors: **Kenneth K. Sokoll**, Alton (CA); **Pele Chong**, Richmond Hill (CA); **Michel H. Klein**, Willowdale (CA)

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(73) Assignee: **Aventis Pasteur Limited**, Toronto (CA)

EP 600161 6/1994  
WO WO 94/09760 5/1994

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

#### OTHER PUBLICATIONS

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/331,118**  
(22) PCT Filed: **Dec. 19, 1997**  
(86) PCT No.: **PCT/CA97/00980**

§ 371 (c)(1),  
(2), (4) Date: **Aug. 31, 1999**

(87) PCT Pub. No.: **WO98/28357**  
PCT Pub. Date: **Jul. 2, 1998**

#### Related U.S. Application Data

(63) Continuation-in-part of application No. 08/770,850, filed on Dec. 20, 1996, now Pat. No. 6,082,820.

(51) Int. Cl.<sup>7</sup> ..... **A61K 9/16**; **A61K 47/34**;  
C08G 63/08

(52) U.S. Cl. .... **424/501**; **424/78.37**; **528/318**;  
**528/329.1**

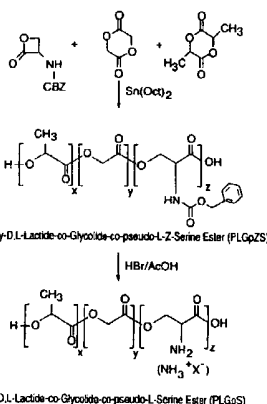
(58) Field of Search ..... **424/426**, **443**,  
**424/78.37**, **501**; **514/772.3**; **525/54.11**; **528/283**,  
**288**, **315**, **318**, **329.1**

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L6: Entry 1 of 25

File: PGPB

Feb 19, 2004

DOCUMENT-IDENTIFIER: US 20040033240 A1

TITLE: Immunological combinations for prophylaxis and therapy of helicobacter pylori pylori infection

Detail Description Paragraph:

[0041] Adjuvants to be used in vaccine formulations for prevention and treatment should provide a "balanced" Th1/Th2 response, a profile likely to be associated with protective responses against *H. pylori*. The Th1 arm (a "cellular" response) has been shown to be critical in response to *H. pylori* infection. The Th2 arm (an "antibody" response) is also thought to be important. Thus, ideally, an adjuvant capable of stimulating both arms of the immune system, together with the correct combination of antigens, administered in the route most suited to eliciting the desired response, are all expected to be important components of a safe, efficacious vaccine for prophylaxis and therapy of *H. pylori* infection. One such balanced Th1/Th2 adjuvant is DC-Chol (F. Brunel et al. 1999 Vaccine 17: 2192-2203).